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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/490,643 | 01/24/2000 | Jeremy Minshull | 02-020622US | 7434 |

22798 7590 04/23/2002

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| EXAMINER |
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WHISENANT, ETHAN C

| ART UNIT | PAPER NUMBER |
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1634

DATE MAILED: 04/23/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------|-----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/490,643 | MINSHULL ET AL. |
| | Examiner | Art Unit |
| | Ethan C. Whisenant | 1634 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 07 January 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 31-82,84-104,106-148 and 150-169 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 31-82,84-104,106-148 and 150-169 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8. 6) Other: _____.

DETAILED ACTION

1. The applicant's Response (filed 07 JAN 02) to the Office Action has been entered. The applicant's response was received on 28 JAN 02 and has been entered as paper no. 15. The claims pending in this application are **Claim(s) 31-82, 84-104, 106-148, 150-169**. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

REASON FOR ALLOWANCE

2. **Claim(s) 31-82, 84-104, 106-148, 150-169** is/are allowable over the prior art of record because the prior art considered does not teach or reasonably suggest the methods for mutagenizing a target nucleic acid as recited in Claims 31 and 33. In particular, the closest prior art Hartley et al. [US Patent No. 6,270,969(2001)] do not teach or reasonably suggest, either alone or in combination with the other prior art considered, the methods for mutagenizing a target nucleic acid as recited in Claims 31 and 33. Claim 31 is patentably distinct from Hartley et al in that these authors do not teach or reasonably suggest, either alone or in combination with the other prior art considered, conjoining a plurality of homologous recombination sites to a plurality of subsequences of at least one nucleic acid in order to produce a plurality of recombination cassettes.

Claim 33 is patentably distinct from Hartley et al in that these authors do not teach or reasonably suggest, either alone or in combination with the other prior art considered, conjoining at least one homologous recombination site to a plurality of the functionally similar subsequences in order to produce a plurality of recombination cassettes.

Note that Hartley et al. is considered prior art in that they disclose their method of cassette mutagenesis in 08/486,139 filed 07 JUN 1995 whereas the earliest disclosure date that can be accorded Claims 31 and 33 is 20 MAY 1996 with the filing of 08/650,400.

DOUBLE PATENTING

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759

F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. **Claim(s) 31-82, 84-104, 106-148, 150-169** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-36 of U.S. Patent No. 5,837,485. Although the conflicting claims are not identical, they are not patentably distinct, therefore the granting of a patent on **Claim(s) 31-82, 84-104, 106-148, 150-169** of the instant application would improperly extend the "right to exclude" previously granted in U.S. Patent No. 5,837,485.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

5.. Applicant's arguments with respect to the claimed invention have been fully and carefully considered and are deemed to be persuasive.

CONCLUSION

6.. **Claim(s) 31-82, 84-104, 106-148, 150-169** is/are rejected and/or objected to for the reason(s) set forth above.

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



**ETHAN C. WHISENANT
PRIMARY EXAMINER**